IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of: **MATSUZAKI, Koichi, et al.**

Group Art Unit: **1642**

Serial No.: **10/822,860**

Examiner: **Gary B. NICKOL**

Filed: **April 13, 2004**

P.T.O. Confirmation No.: 2658

For: **ANTIBODIES SPECIFIC FOR PHOSPHORYLATION SITES AND SCREENING METHODS USING THE SAME ANTIBODIES**

RESPONSE TO THE RESTRICTION REQUIREMENT DATED September 6, 2006

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Date: October 31, 2006

Sir:

This paper is submitted in response to the Official Action dated **September 6, 2006**, the period for response being extended by a petition for a one-month extension of time.

In the Action, restriction is required between Groups I to XIX, as defined in the Office action dated September 6, 2006. Applicant hereby elects **Group II** (claims 1-5 drawn to a polyclonal antibody specific for a phosphorylated linker region in Smad 3) **with traverse** of the restriction requirement, as explained below.

Regarding the restriction between Group II and Groups I and III

In Groups I to III, the Examiner is restricting **within each claim** between the three cases of the target for the antibody (i.e., Smad2, Smad3 and both Smad2 and Smad3). Applicant submits that this is a restriction between alternatives, and is analogous to restriction within a Markush group. In

this regard, MPEP 803.02 states that "if the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner **must examine all the members of the Markush group on the merits, even though they may be directed to independent or distinct inventions**" (emphasis added). The present case is, in effect, is a Markush group **with only three members** (as defined by the Examiner), and, in fact, requires search only of the Smad2 and Smad3 cases, since the search for the case of both Smad2 and Smad3 would be included in the searches for Smad2 and Smad3. Applicant therefore submits that the search can be made without serious burden, and that all of Groups I, II and III should be examined.

Regarding the restriction between Group II and Groups IV to XIX

The Examiner restricts between Groups I to III and Groups IV to XIX as being a restriction between product and process of use. Applicant submits, however, that the search for the polyclonal antibodies of Groups I to III would inherently encompass a search for methods of use of these polyclonal antibodies, and that the additional search burden is therefore negligible. In addition, if the polyclonal antibodies of Groups I to III are found to be not anticipated and not obvious, any method using these specific polyclonal antibodies would also be not anticipated and not obvious.

Regarding the restriction between Groups VIII to X

Groups VIII to XIII correspond to claim 11, restricted within the claim first between the antibodies of Groups I to III, and further between groups VIII to X as being directed to "a method for assessing the efficacy of **fibrosis stimulating signal**" and groups XI to XIII as being directed to "a method for assessing the efficacy of the molecular targeting therapy for **hepatic fibrosis**." Applicant has argued above traversing the restriction between Groups I to III, and Applicant here argues against the restriction on the basis of the claims being directed to separate methods.

The preamble of claim 11 recites a **single method** that is for assessing the efficacy of fibrosis stimulating signal and assessing the efficacy of the molecular targeting therapy for hepatic fibrosis. There is **no difference in the steps of claim 11** corresponding to these two purposes. (Note that step (i) of claim 11 requires collecting a tissue sample of both hepatic fibrosis and drug-treated hepatic fibrosis). Applicant therefore submits that the stated restriction, which is based only on the wording of the preamble, is improper.

Applicant has presented arguments traversing all of the restriction requirements imposed by the Examiner, and Applicant respectfully requests withdrawal of the restriction requirement, rejoinder of the restriction groups, and examination of all of the claims.

In the event that this paper is not timely filed, Applicant hereby petitions for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 01-2340.

In the event any additional fees are required in connection with this response, please charge our Deposit Account No. 01-2340.

Respectfully submitted,

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